

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/512, 082 02/24/00 NERI

D SCH-1733-P2

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EXAMINER

PORTNER, V

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

08/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/512,082	Applicant(s) Neri et al
Examiner Portner	Group Art Unit 1645

 Responsive to communication(s) filed on Feb 24, 2000 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims Claim(s) 1-35 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

 Claim(s) _____ is/are allowed. Claim(s) _____ is/are rejected. Claim(s) _____ is/are objected to. Claims 1-35 are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-34 are pending.

Oath/Declaration

1. This instant Application claims priority to two US Applications now pending in the United States Patent Office, and states that the Application claims foreign priority under 35 U.S.C. 119. The priority claimed is not foreign priority. Clarification of the priority claimed is requested.

2. If applicant desires priority under 35 U.S.C. 119 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now patent no." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. The first sentence of the specification does not refer to the priority documents upon which Application is based; amendment of the specification to reflect the foreign priority entitled to this Application is requested.

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Sequence Letter

3. This application contains Sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

4. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.136. In no case may an applicant extend the period of response beyond the six month statutory period and the response period is the time set in this action. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

5. Sequences which need assignment of a SEQ ID NO were found at page 3, lines 16-18; page 19, lines 23, 26-28, 30-31; page 23, lines 2-4, 6-8, 11-13 and 31; page 24, lines 1, 3-4 and 7; page 34, Table 1, Claims 7 and 10 and Figures 1 and 6.

Specification

The disclosure is objected to because of the following informalities: At page 15, lines 5 and 7, hyperlinks to sites on the Internet are recited. This is not permitted in a US Application. Appropriate correction is required.

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Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Election/Restriction

7. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13 and 18 are, drawn to antibodies which specifically bind to a fibronectin and a kit comprising said antibodies, classified in class 530, subclass 387.1 .
- II. Claims 14-17, drawn to a methods of detecting fibronectin ED-B domain, either in vivo or in vitro associated with tumors, diabetes, macular degradation , classified in class 435, subclass 7.1.
- III. Claim 19, 25-27 (in vivo applications only), drawn to in vivo therapy associated with treating a host with an antibody, classified in class 424, subclass 158.1.
- IV. Claims 20-34 are, drawn to antibodies conjugates and methods of using the conjugate antibodies for treatment of angiogenesis, classified in class 424, subclass 178.1.
- V. Claim 35 is, drawn to a trimethylstannylbenzoic acid classified in class 424, subclass 1.73 .

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8. The inventions are distinct, each from the other because of the following reasons:
9. Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case ^{the} product as claimed can be used in a materially different process of using that product, wherein the antibodies of Group I may be used for in vivo or in vitro detection of fibronectin as well as in the immunotherapy of a host with antibodies which specifically provide a therapeutic effect in vivo, as well as in method of purifying antigen to which the antibodies specifically bind.
10. Inventions Group I and Group IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as antibodies for incorporation into diagnostics, in methods of purifying a protein and in the production of molecular image polymers the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibodies of Group I and the organic stannylbenzoic acid do not share any structural, functional or biological effects in common and therefore define independent and distinct inventions.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
August 14, 2000


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- 7. Other: _____

Applicant Must Provide:

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE